AUG 3 0 2001

K011747

Attachment 5

510(K) Summary of Safety and Effectiveness

This 510(K) Summary of Safety and Effectiveness for the LC100 Diode Array Laser System is submitted in accordance with the requirements of Safe Medical Device Act (SMDA) of 1990 and follows the Office of Device Evaluation (ODE) guidance concerning the organization and content of a 510(K) summary.

Applicant:	Palomar Medical Technologies, Inc.
Address:	82 Cambridge St. Burlington, MA 01803
Contact Person:	Marcy Moore
Telephone:	919-363-2432
Preparation Date:	June 1, 2001
Device Trade Name:	Palomar LC100
Common Name:	Super Long Pulse Diode Laser
Classification Name:	Laser surgical instrument for use in General and Plastic Surgery and in Dermatology (see: 21 CFR 878-4810). Product Code: GEX Panel: 79
Legally-Marketed Predicate Device:	Palomar SLP 1000 Diode Laser Palomar Medical Technologies, Inc. K994225; K010580 LightSheer Diode Array Laser Star Medical Technologies, Inc. K973324, K974346, K982940, K001746, K003614
System Description:	The LC100 delivers infrared laser light with a wavelength of 810 nm, a selectable pulse duration of 50 – 1000 ms. The corresponding fluence is delivered through a 12x12 or 12x6 mm handpiece

tip. The laser pulses are generated at a maximum pulse repetition frequency of 3.3 Hz.

The complete system consists of a, chiller, a footswitch, and a handpiece containing diode bars connected to the power unit with an umbilical. In standard use, the handpiece is pressed against the patient's skin and a light pulse is delivered when the footswitch is depressed. The handpiece tip is water-cooled to provide active skin cooling. Laser parameters and other system features are controlled from the user interface panel on top of the laser unit, which provides an interface to the system computer.

Intended Use of the Device:

The LC100 Diode Laser System is indicated for haire removal, permanent hair reduction, treatment of pigmented and vascular lesions, including leg veins, and incision/excision, ablation and coagulation of soft tissue (for patients with skin types I-VI, including tanned skin).

Performance Data:

The differences in the specifications of the LC100 laser and the predicate device do not result in different performance or raise new questions of safety or efficacy.

Conclusion:

Based on the foregoing, the LC100 Diode Array Laser System is substantially equivalent to the legally-marketed claimed predicate device, i.e., the SLP1000™ and LightSheer™ diode lasers.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 0 2001

Palomar Medical Technologies, Inc.
c/o Ms. Marcy Moore
131 Kelekent Lane
Cary, North Carolina 27511

Re: K011747
Trade/Device Name: Palomar LC100
Regulation Number: 878.4810
Regulatory Class: II
Product Code: GEX
Dated: May 31, 2001
Received: June 5, 2001

Dear Ms. Moore:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Susan Walker M.D. for

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(K) Number: K011747

Device Name: Palomar LC100

Indications for Use:

The LC100 diode laser system is indicated for hair removal and permanent hair reduction. Permanent hair reduction is defined as a long-term, stable reduction in the number of re-growing hairs after a treatment regime.

The LC100 is also indicated for photocoagulation of dermatological vascular lesions, including port wine stains, telangiectasia, angioma, hemangioma, spider nevi, and other benign vascular lesions; photothermolysis of blood vessels (treatment of facial and leg veins); removal of benign pigmented lesions, including lentigines, nevi, chloasma, and café-au-lait; incision/excision, ablation and coagulation (homeostasis) of soft tissue.

The LC100 is indicated for use in patients with skin types I-VI, including tanned patients.

(Please do not write below this line - Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use ____
(per 21 CFR 801.109)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011747